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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,598	12/05/2003	David R. Anderson	18438/09038 (0115/2)	1565

7590 07/16/2004
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P.O. Box 11070
Columbia, SC 29211-1070

EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/729,598

Applicant(s)

ANDERSON ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-20 are pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, last eight compounds (see pages 111-112) do not read upon compounds of claim 1. Although claim 8 is an independent claim yet instant compounds are searched based on the common core structure of claim 1 having amino groups at 2 and 4 positions and CN group at 3rd position. The applicants are suggested to delete these compounds or they will be restricted in the next office action since they do not read upon the common core of compounds of claim 1 and therefore, constitutes a burdensome search.

Claims 9-11 recite the limitation "prodrugs, salts, tautomers and combinations thereof" in claim 8. There is insufficient antecedent basis for this limitation in the claim.

In claims 9-11, the term ---prodrugs --- is indefinite since specific prodrugs and methods of preparing them are not defined.

In claim 12, the term --capable -- is indefinite since it is not clear whether it does inhibit activity of MK-2 or does not inhibit it and furthermore, is it in vitro inhibition or in vivo inhibition?

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In claims 13 and 14, the term ---provides---is vague. The applicants are suggested to use the term ---demonstrates or has --- as appropriate. Also, is it in vitro assay or in vivo assay?

In claims 15 and 16, the term --provides a TNF alpha release --- is vague. The applicants are suggested to use the term ---demonstrates an IC50 value of below 200uM for inhibiting TNF alpha release in an in vitro cell assay----.

In claims 17 and 18, the term ---provides a degree of inhibition of TNF alpha in a rat LPS assay of at least about 25% or above 80%----is vague. The applicants are suggested to use the term ---inhibits TNF alpha release in vivo by at least 25% or 80% in a rat LPS assay ---.

In claim 20, the term ---dosage form --- is indefinite since the dose as well as form (for intraperitoneal use or intravenous use or intramuscular use or subcutaneous use or intramuscular use or oral use etc.) is not defined.

Applicants are suggested to cancel claims 12-18 and 20 since they are directed to mechanism of their action and not any utility and therefore, do not add any thing to compound or pharmaceutical composition claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-11, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Callaghan (J/Chem. Res., perkin transactions 1).

O'Callaghan discloses benzopyrano[2,3-b]pyridine derivatives. The compound no. 3 where R represents either H or methoxy (see page 417) disclosed by O'Callaghan

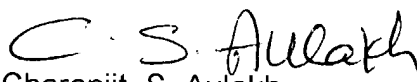
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anticipates the instant claims when both R1 and R2 represent H, G represents O, R8 represents H or methoxy and either R3 or R4 represents dicyano C1 alkyl or dicyano C2 alkyl (homolog compound) group in the instant compounds of formula of claim 1.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
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